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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,539	07/16/2003	H. William Bosch	029318-0961	6324
31049 7590 02/07/2007 ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON, DC 20007-5109			EXAMINER TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/07/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/619,539

Applicant(s)

BOSCH ET AL.

Examiner

Susan T. Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-123 is/are pending in the application.
- 4a) Of the above claim(s) 46-123 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>all</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-45) in the reply filed on 10/24/06 is acknowledged. The traversal is on the ground(s) that the search and examine of three groups is not unduly burdensome. This is not found persuasive for the following reasons:

Distinctness between a process of making and the product made is shown if "the product as claimed can be made by another materially different process." MPEP § 806.05(f). In the restriction requirement, the examiner set forth several "materially different processes" by which the claimed product could be made.

A serious burden on the examiner is shown according to the criteria of MPEP § 808.02, where one of the following must be supported by appropriate explanation:

1. Separate classification thereof:

This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search,. Patents need not be cited to show separate classification.

2. A separate status in the art when they are classifiable together; and
3. A different field of search....

In the restriction requirement of 08/30/06, the examiner set forth separate classification for the three inventions to which claims were presented. Applicant has not alleged that the claims were improperly classified. Nor has applicant alleged that the

Art Unit: 1615

classifications set forth are not "separate classifications." Thus, requirement 2 of MPEP § 803 is met. For these reasons set forth above, the restriction requirement is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 46-123 withdrawn from further consideration pursuant to 37 CFR

1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/24/06.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-40, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are rejected because they do not identify the structure, material, or acts set forth in the specification that would be capable of carrying out the functional properties recited in the claims. It appears that the specification does not provide adequate teaching and/or support as to how the composition can result in the claimed release profile,  $C_{max}$ ,  $T_{max}$ , and

Art Unit: 1615

bioequivalency. Accordingly, the structure which makes up the formulation must be clearly and positively specified.

Claims 35-40, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims lack the description of the possible genus with the recited functional characteristics.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 24, 32-35, 37 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 contains the trademark/trade name "POLYQUAT <sup>TM</sup>" or "MIRAPOL <sup>TM</sup>" or "ALKAQUAT<sup>TM</sup>". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Claim 13 recites the limitation "the liquid media of the liquid dosage composition" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claims 32-34 recite the limitation "the viscosity" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 35 recites the limitation "the  $T_{\max}$ " in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 recites the limitation "the  $C_{\max}$ " in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 39 recites the limitation "the AUC" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 10-15, 18 and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Na et al. US 5,298,262.

Na discloses a composition comprising active-containing nanoparticles having a surface modifier adsorbed on the surface thereof and a non-ionic cloud point modifier associated therewith (abstract). Column 2, line 1 through column 3, lines 1-11, disclosed the claimed surface modifier. Surface modifier is used in an amount 0.1-90%

Art Unit: 1615

(column 4, lines 53-68). The composition further comprises isotonicity maintaining compounds include mannitol, dextrose, and sodium chloride (crystal growth inhibitor) (column 6, lines 29-32). Na further teaches the nanoparticle has an effective average particle size of less than about 400 nm (column 5, lines 8-28).

Claims 1-5, 8-15 and 17-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Na et al. EP 0601619 (Na 2).

Na discloses a nanoparticulate composition comprising active agent, surface modifier adsorbed on the surface thereof and 0.01-50% of a non-ionic cloud point modifier (crystal growth inhibitor) (abstract; and page 5, lines 26-27). Surface modifier is disclosed in page 2, lines 54 through page 3, lines 1-34. Na further discloses the use of two or more surface modifier (page 3, lines 34-35). Cloud point modifier includes glycerol (page 5, lines 15-18).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Na and Na 2, in view of Liversidge US 2005/0004049.

Na and Na 2 are relied upon for the reasons stated above. The cited references do not explicitly teach the claimed active agent, as well as the claimed properties, such as Cmax, Tmax, bioequivalent, and viscosity.

Liversidge teaches a nanoparticulate composition comprising surface modifier, and a drug having solubility of less than about 30 mg/ml (abstract; and paragraph 0045). Drug including analgesic, NSAID and vitamins are disclosed in paragraphs 0109-0113). The claimed surface modifier, and combination of two or more surface modifier is disclosed in paragraphs 0124-0144). Liversidge also teaches the claimed effective particle size in paragraphs 0161-0162. The nanoparticulate composition is processed into a liquid dosage for bioadhesive composition (paragraphs 0081-0089). Liversidge further teaches the claimed viscosity, Cmax, Tmax, and bioequivalency (paragraphs 0090-0105). Thus, it would have been obvious to one of ordinary skill in the art to modify the nanoparticulate compositions of Na and Na 2 in view of the teachings of Liversidge to obtain the composition, because Liversidge teaches a nanoparticulate composition that is advantageous to a pharmaceutical art, such as improve clinical efficacy, reduce fed/fasted variability, and potentially reduce side effects (paragraph 0028), because Na and Na 2 teach a nanoparticulate composition suitable for a variety of drugs, and because Na and Na 2 teach the desirability to obtain a nanoparticulate composition useful in pharmaceutical art.



Art Unit: 1615

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN  
PRIMARY EXAMINER



Art Unit 1615